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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,379		Feng Xu	10046.200-US	4004

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NOVOZYMES BIOTECH, INC.
1445 DREW AVE
DAVIS, CA 95616

EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/04/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,379

Applicant(s)

XU, FENG

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-10,12,13,15-18,22,25,28 and 32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-10, 12-13, 15-18, 22, 25, 28, and 32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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The application should be reviewed for errors. Error occurs, for example in the spelling of "*Burkholderie*" in claim 7.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 12-13, 15-18, 22, 25, 28 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 lacks proper antecedent basis in claim 6 for "the aerobic bacteria^a". Claim 8 lacks proper antecedent basis for "the anaerobic bacteria^a".

Claim 18 lacks proper antecedent basis for in claim 1 for "the effective concentration of one or more acylases". Claim 1 pertains to "an effective amount of a composition comprising..."

Claim 28 lacks proper antecedent basis for in claim 1 for "the surface is contacted with the one or more acylases". Claim 1 pertains to "contacting the surface with an effective amount of a composition comprising..."

Claim 7 is confusing in that the distinction between *Pseudomonas* and *Burkholderia* is unclear.

Claim 16 is confusing in that the distinction between *Yarrowia* and *Candida* is unclear.

Claim 18 is vague and indefinite in that the nature of one or more acylases effective to eliminate biofilms at a concentration of 0.001 g of acylase per kilogram of water is not ascertainable, even when interpreting the claim in light of the specification. In addition, the activity of the acylase intended is not indicated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12-13, 18, 22, 25, 28, and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wiatr.

The claims are directed a method of eliminating microbial biofilm on a surface wherein the surface is contacting with a composition comprising acylases such that the degradation of a lactone results in elimination of biofilm.

Wiatr discloses a method of eliminating microbial biofilms on surfaces wherein the surfaces are contacted with an enzyme composition comprising acylases such that the degradation of a lactone results in elimination of biofilm. See, e.g., Table II, wherein the effective use of the acylases neutral protease and alkaline proteases is disclosed. The use of other enzymes is noted. At least temperature and pH parameters are within the required ranges. Similarly, it is presumed that at least the lower level of acylase concentration is met by the reference, particularly in the absence of evidence to the contrary.

Claims 1-10, 12-13, 15, 17-18, 22, 25, 28, and 32 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hollis *et al.*.

The claims are directed a method of eliminating microbial biofilm on a surface wherein the surface is contacting with a composition comprising acylases such that the degradation of a lactone results in elimination of biofilm.

Hollis *et al.* discloses a method of eliminating microbial biofilms on surfaces wherein the surfaces are contacted with an enzyme composition comprising acylases such that the degradation of a lactone results in elimination of biofilm. See, e.g., Examples 1 and 7 wherein the effective use of the acylases, i.e. acidic and alkaline proteases are used to eliminate biofilm. The use of surfactants and other enzymes is noted. At least temperature and pH parameters are within the required ranges. Similarly, it is presumed that at least the lower level of acylase concentration is met by the reference, particularly in the absence of evidence to the contrary.

Claims 1-10, 12-13, 15-18, 22, 25, 28, and 32 rejected under 35 U.S.C. 102(a) as being clearly anticipated by Berka *et al.*.

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The claims are directed a method of eliminating microbial biofilm on a surface wherein the surface is contacting with a composition comprising acylases such that the degradation of a lactone results in elimination of biofilm.

Berka *et al.* discloses a method of eliminating microbial biofilms on surfaces wherein the surfaces are contacted with an enzyme composition comprising acylases such that the degradation of a lactone results in elimination of biofilm. See, e.g., page 36, lines 25-30 wherein the effective use of the acylases is disclosed. At least temperature and pH parameters are within the required ranges. Similarly, it is presumed that at least the lower level of acylase concentration is met by the reference, particularly in the absence of evidence to the contrary.

Claims 1-10, 12-13, 15-18, 22, 25, 28, and 32 rejected under 35 U.S.C. 103(a) as being unpatentable over Wiatr taken with Hollis *et al.* and Allison *et al.*.

Wiatr and Hollis *et al.* each discloses a method of eliminating microbial biofilms on surfaces wherein the surfaces are contacted with an enzyme composition comprising acylases such that the degradation of a lactone results in elimination of biofilm. See, e.g., Table II and Examples 1 and 7, wherein the effective use of the acylases such as acidic, neutral and alkaline proteases is disclosed. At least temperature and pH parameters are within the required ranges. Similarly, it is presumed that at least the lower level of acylase concentration is met by the reference, particularly in the absence of evidence to the contrary.

With respect to sources of acylases, Hollis *et al.* and Wiatr use enzymes obtained from fungal and bacterial sources. There references are silent about the use of enzymes from a yeast source. However, it is apparent from the present written disclosure that the data presented is directed to the reduction of microbial growth in an aquarium using porcine kidney acylase I at a certain concentration and after a certain period of time, rather a microbial enzyme. See, e.g., Specification, Tables I and II.

With regard to the involvement of homoserine lactones in biofilm structure and formation, Allison *et al.* discuss the content of N-acyl-hexanoyl homoserine lactone in biofilms and its role in biofilm formation (See, e.g., Figure 1). The reference also strongly suggests that enzymic degradation provides a means to achieve cell detachment from the biofilm (See, e.g., page 184, last paragraph). Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in using an acylase as taught by Hollis *et al.* and Wiatr to eliminate a variety of biofilms in industrial and therapeutic settings.

It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process Wiatr and Hollis *et al.* by using enzymes capable of hydrolyzing N-acyl-hexanoyl homoserine, such as acylases and in particular, lactonohydrolases,

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for the expected benefit of decreasing biofilms on surfaces in both industrial and therapeutic applications, such as biofilms of piping, heat exchangers, food process, potable water systems and in the treatment of dental caries, periodontal disease, cystic fibrosis, etc.

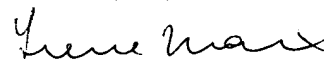
Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
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